

K960639

Pre-Market Notification  
February 7, 1996  
Page -2-

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MAY 14 1996

**VI. 510(k) Summary of Safety and Effectiveness**

**A. Name and Address**

This Summary of Safety and Effectiveness is being submitted by Nobelpharma USA, Inc., 777 Oakmont Lane, Suite 100, Westmont, IL 60559. Their telephone number is: (708) 654-9100 and the contact person will be the Director, Regulatory Affairs. This summary was prepared on February 7, 1996.

**B. Name of the Device**

The device is generally known as trial model abutments used for fitting purposes, and will have the trade name "BRANEMARK SYSTEM® Abutment Selection Kit."

**C. The Predicate Product**

The predicate products used in this Premarket Notification is the abutment selection kit, K944963.

**D. Description of the Device**

The Nobelpharma BRANEMARK SYSTEM® Abutment Selection Kit consists of trial models of various abutments which are used by the practitioner to select the proper abutment. It can be used in two situations: in a patient's mouth and/or on a plaster model. The abutment selection system is used in a patient's mouth for only 5-10 minutes so that the clinician can determine the proper abutment type and length.

**E. Intended Use of the Device**

The Nobelpharma BRANEMARK SYSTEM® Abutment Selection Kit is intended to be used by practitioners to select the proper abutment.

**F. Comparison of Technological Characteristics**

The technological characteristics between the two Abutment Selection Kits are identical. The proposed colorant method is used to provide a bright color distinction between the "trial" abutments and the abutments intended for long-term use.